PRESS RELEASE

NERVIANO MEDICAL SCIENCES

PART OF NMS GROUP

Nerviano Medical Sciences Receives FDA "Study May Proceed" Letter for First-In-Human Phase 1 Clinical Trial under Its Investigational New Drug Application for NMS-03602173, a Dual IDH1/2 Inhibitor, in Advanced Solid Tumors

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Nerviano Medical Sciences (NMS Srl,) a member of NMS Group and a pharmaceutical company developing innovative new chemical entities (NCE) for the treatment of cancers, today announces that the U.S. Food and Drug Administration (FDA) has accepted its Investigational New Drug (IND) application to evaluate NMS-03602173, a second-generation oral inhibitor of IDH1 and IDH2, in advanced solid tumors.

"The go-ahead received from FDA to initiate a Phase 1 trial with NMS-03602173 accelerates our race against IDH1/2-mutated cancers," said Gregory Wu, Ph.D., CEO of NMS Srl. "Inhibiting IDH1/2 mutant enzymes is a validated therapeutic approach and FDA-approved IDH inhibitors have shown a benefit for a subset of cancer patients. However, the therapeutic responses obtained so far are modest, particularly in solid tumors," said Wu. "NMS-03602173 was fully discovered and developed by our team, and is a potential Best-In-Class, second-generation dual inhibitor of mutant IDH1/2 aiming to provide more durable clinical benefits to a broader patient population worldwide with IDH-mutant solid tumors."

"NMS-03602173 has a distinctive mode of action and superior activity with a favorable safety profile in preclinical studies, compared to approved IDH inhibitors. We believe that these features will translate into improved clinical efficacy to overcome the resistance to first-generation IDH inhibitors and increase life expectancy of cancer patients with IDH1 and IDH2 mutations." added Frank Gan, Pharma D., Head of Global Clinical Development at NMS Srl.

Under this IND, NMS-03602173 will be initially tested in a Phase 1, First-In-Human (FIH) study (IDHA-173-001) as a single agent for adult patients with IDH-mutated advanced/metastatic solid tumors, including cholangiocarcinoma, which have exhausted standard treatment options. The primary objectives of the trial are to determine the maximum tolerated dose and the recommended dose for further study as well as the general safety profile and tolerability. Exploratory objectives include pharmacodynamic and predictive biomarkers analysis.

About NMS-03602173

NMS-03602173, fully discovered and developed by NMS Srl, is a potent, highly selective and orally available investigational new drug for the treatment of patients with IDH1 and IDH2 mutated solid tumors, including low grade gliomas, cholangiocarcinoma, and chondrosarcoma. Mutant isocitrate dehydrogenase enzyme (IDH) enzymes are driver oncogenes in different types of solid tumors and hematologic malignancies, due to their gain-of-function activity that results in accumulation of the oncometabolite d-2-hydroxyglutatrate (2-HG). NMS-03602173 showed the ability to decrease intracellular levels of 2-HG and to induce cell differentiation and tumor growth inhibition in models of IDH1and IDH2 mutated tumors in preclinical studies.

About Nerviano Medical Sciences

Nerviano Medical Sciences S.r.l. (NMS Srl) is focused on discovery and clinical development of small molecule NCEs for oncology. We take innovative approaches on novel mechanisms of action and drug targets to bring first- and best-in-class personalized medicines to cancer patients. Our current pipeline consists of NCEs, which all originate from our well validated kinase platform that span from early preclinical to clinical stage projects and which are being developed both in house and with partners.

NMS Srl combines the flexibility of a biotech with the quality of a big pharma. Here, an experienced management team leads a highly skilled staff of professionals with global vision and a broad range of expertise in research, drug discovery and clinical development. We cover the whole range of additional aspects of drug development through the NMS Group affiliate companies, Accelera (AdMet) and NerPharMa (manufacturing).

A key strength is our industrially renowned kinase inhibitor drug discovery platform which comprises an ever-evolving chemical collection with broad intellectual property coverage, discovery know-how and technologies which enabled us to out-license IP rights on recently approved innovative medicines such as encorafenib and entrectinib.

We collaborate with academia and clinical investigators as well as with industrial partners worldwide to advance our programs from early discovery to clinical development of new drugs. We seek further strategic collaborations to develop and commercialize our products in different territories as well as in-licensing opportunities of promising assets for clinical development.

About NMS Group

NMS Group is the largest oncological R&D company in Italy. With more than 400 employees of whom more than half are highly educated individuals dedicated to innovative research, development and manufacturing. The NMS kinase inhibitor discovery platform as well as the antibody-conjugating payload platform are the driving forces of the group's innovation, securing global recognition of NMS in personalized therapy. Recently entrectinib, originally discovered by NMS, is a targeted kinase inhibitor to treat NTRK1/2/3 and ROS1 dependent solid tumors that was licensed to Ignyta, now a member of the Roche Group, gained approvals for commercialization in all major markets. This is further evident of the competitiveness of the drug discovery platform of NMS Group.

NMS Group has three subsidiaries. NMS S.r.l. is a FIC / BIC focused drug research and development company with a robust pipeline of more than a dozen of anti-cancer projects, and three of the projects are currently in early clinical development. The other two subsidiaries are Accelera, which is a preclinical CRO company, and NerPharMa which manufactures API and drug product supporting clinical developments and commercialization.

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